

Remarks

Request for Reconsideration Pursuant to 37 C.F.R. § 1.116

This invention and the rejected claims (as amended) are directed to a new and unique system for treating people suffering from insomnia. The system implements behavioral therapies for treating insomnia using information indicative of the subject's wake/sleep state. As explained in the specification and set forth in the rejected claims, insomnia for purposes of the present invention includes difficulty falling asleep, difficulty staying asleep, or waking too early. The behavioral therapies implemented in the system include stimulus control therapy, sleep restriction therapy and relaxation therapy. The preferred behavioral therapy is stimulus control which curtails overt and covert sleep incompatible activities that serve as cues for staying awake and by enforcing a consistent wake and sleep schedule. Sleep restriction therapy consists of curtailing the amount of time spent in bed to match the subject's subjective sense of their amount of sleep. These behavioral therapies are discussed at page 2, line 5 to page 3, line 22 of the specification.

Thus, for example, when the system of the present invention implements stimulus control therapy, it determines whether the non-sleeping subject should get out of bed in order to advance the insomnia treatment therapy and if it makes such a determination it alerts the non-sleeping subject to leave the bed. (*See*, e.g., specification at page 16, lines 11-19, Fig. 1 and claim 48). Detailed parameters regarding when to alert the subject are set forth, for example, in claims 44 and 45. The system also acquires information as to whether the subject is in bed or not along with wake/sleep state information (e.g., claim 55). The system additionally chooses the behavioral therapy to be implemented based on the subject's wake/sleep information (e.g., claim 40).

When following stimulus control rules, the present invention monitors the subjects' wake/sleep history. If it determines that the subject is asleep, it does not generate an alarm. In fact, in implementing the stimulus control therapy it never wakes a sleeping subject! This is completely at odds with the purpose of an alarm clock (e.g., Halyak which is discussed below) to awaken a sleeping subject. This key distinction is further driven home by the fact that if the present invention detects that the user has been awake for a period of time an alert may be generated to get the subject out of bed. This alert is generated to cause the already awake subject to perform an action, not to awaken the subject. In fact, if the subject were asleep, no alert would be generated.

The centerpiece of the current Office Action (and the previous Office Action) rejecting virtually all of the previously pending claims is U.S. Patent No. 5,928,133 to Halyak. Halyak teaches nothing whatsoever regarding either behavioral therapy or treating subjects suffering from insomnia. In fact, Halyak does not claim to provide any treatment whatsoever. Halyak generates an alarm during a pre-set time interval to get a user out of bed in the same manner as a standard alarm clock, with the exception that it tries to choose a time when the user is lightly asleep and hence most easily awoken. The device does not take wake/sleep information or sleep history into account (how much time spent awake or asleep) as is necessary to implement the behavioral therapies in the present invention. The Halyak alarm clock will alert the subject within the same time interval every day that it is used. Halyak generates the alarm to wake the subject from sleep and for no other purpose. Halyak is not, and never claims to be treating a medical condition such as insomnia and the device does not provide any treatment or therapy.

Thus, as explained in the Abstract of the Halyak patent and throughout its specification, Halyak is concerned only with awakening a user during a preset time interval when, for all intents and purposes, the user is already awake. In other words, Halyak's contribution is an improved alarm clock that (allegedly) monitors the user's sleep to determine when the user can be most easily awoken and then delivers an alarm signal to wake the user from sleep.

The Examiner cannot meet his burden of presenting a *prima facie* showing of obviousness based on the teaching of Halyak, either taken alone or in combination with other references. This is because, *inter alia*, one skilled in the art would not look to an alarm clock (as in Halyak) to treat someone suffering from insomnia, essentially the inability to fall asleep! And, combining the Halyak alarm clock with the insomnia monitor of Pardey et al., as proposed by the Examiner, would produce a nonsensical result unrelated to the present invention.

The Examiner makes a key admission on page 4 of the Office Action: "Halyak....fails to teach of the sleep monitoring device being used to assist those suffering from insomnia." All other statements regarding Halyak are incorrect, as summarized in the table below:

Examiner's Position	Why This is Incorrect	Claims
Halyak teaches an automated system for facilitating the implementation of behavioral therapy that uses information indicative of a subject's wake/sleep state to improve the subject's sleep or sleep hygiene.	<ol style="list-style-type: none"> 1. Halyak does not implement any behavioral therapy. 2. Halyak does not improve the subject's sleep or sleep hygiene – it just delivers an alarm signal to wake the user at a time when he/she is most easily awoken. 	33-41, 43, 46-54, and 58-69
Halyak teaches passive wake/sleep determination means for producing information indicative of the subject's wake/sleep state (column 2, lines 49-58).	Halyak determines whether the subject is close to the beginning or end of REM sleep. This is not indicative of the subject's wake/sleep state.	33-41, 43, 46-54, and 58-69
Halyak teaches means for implementing the steps of the behavioral therapy utilizing the wake/sleep information (column 4, lines 11-24).	Halyak does not implement any therapy, behavioral or otherwise. Col. 4, lines 11-24 simply refers to an apparatus for processing the "electrical resistance of the user" (in Ohms) to determine (according to Halyak) whether the user is at a point in their sleep when an alarm may be sounded "to wake the user with almost no effort at all." (Col. 2, lines 53-58).	33-41, 43, 46-54, and 58-69

Examiner's Position	Why This is Incorrect	Claims
Halyak teaches a combination of therapies is taught (<i>sic</i>) in column 2, line 59 to column 3, line 3, wherein information of the stimulus and restriction/relaxation are used.	Not a single therapy is taught at the cited location (or elsewhere in Halyak). The Halyak device is said to provide the user with data regarding awakening points and interruptions in awakening "from factors such as diet, exercise, or stress." Not only is this unsupported by any disclosure as to how it may be achieved, even if such data were available from the Halyak device, there is no suggestion that the data could or should be used in implementing any behavioral therapy.	39-51, 43 and 46
The Halyak system also uses EEGs, heart rate, movement sensors, galvanic skin response, and other parameters for sleep research (column 3, lines 58-67).	The EEGs, heart rate, movement sensors, galvanic skin response, or any other of the common parameters monitored by sleep researchers referred to at column 3, lines 10-15 are to be used only to achieve the sole objective of the Halyak alarm clock- "to wake the user with almost no effort at all."	39-51, 43 and 46
The Halyak user can calibrate the values that are most efficacious for the user (column 5, lines 10-15).	These values pertain to waking the user without effort and not to anything pertinent to implementation of any behavioral therapy or treatment of insomnia as in the present invention.	39-51, 43 and 46

Examiner's Position	Why This is Incorrect	Claims
The Halyak apparatus processes information taken from the group consisting of: EEG, EKG, EMG, EOG, actigraphy, body movement, galvanic skin response, respiratory changes, eye movements and combinations of two or more thereof to determine the subject's wake/sleep state.	From the Examiner's list, Halyak refers only to EEG, body movement, and galvanic skin response, and not to EKG, EMG, EOG, or actigraphy. More importantly, however, resistance (presumably galvanic skin response) is the only parameter actually employed in Halyak and it is not associated or correlated with insomnia or any behavioral therapy.	47
Means for implementing the behavioral therapy utilizing the wake/sleep state information (column 3, line 58 to column 4, line 55).	No behavioral therapy is contemplated or implemented in Halyak.	47
Halyak teaches that the use of an apparatus that can record varying resistance values can determine when a user should be woken up and that time can be calibrated (column 4, lines 38-42 and column 3, lines 27-33) to the user's needs (column 5, lines 1-15) over a length of time (column 4, lines 10-13) that can be viewed on a monitor or printed for a record of the sleep session (column 4, lines 11-24).	Halyak does teach use of an apparatus to determine when a user should be woken up, he teaches an alarm clock with means for determining and choosing when best to deliver an alarm signal to easily/gently awaken the user. Display or recording of the data upon which the determination is made has no relevance to the rejected claims.	48-54, 68-69
The apparatus is capable of being worn by the user (column 4, lines 5-10) and can wake the user with an alarm (column 5, lines 20-23) that alerts the user either after the sleep period has been completed (column 5, lines 16-34) or as a failsafe.	The apparatus is not at all concerned with alerting the user after a particular sleep period has been completed, it is concerned only with delivering an alarm signal when the sleeper is ready to be easily awoken during a pre-set time interval.	48-54, 68-69

As noted earlier, the Examiner acknowledges that Halyak fails to teach the use of a sleep monitoring device to assist those suffering from insomnia. He appears to argue, however, that one skilled in the art could reasonably be expected to combine Halyak's alarm clock with the teachings of U.S. Patent No. 5,999,846 to Pardey et al. to arrive at Applicants' system for treating people suffering from insomnia.

Pardey et al. teach an insomnia or vigilance monitor that measures the quality of a subject's sleep. Although the device claims to provide a physiological monitor that displays an indicator of the degree of insomnia suffered by the subject, the Pardey et al. device still is no more than an insomnia monitor, and not a treatment apparatus or system. Therefore, the combination of Halyak and Pardey et al. would yield an improved alarm clock with an insomnia monitor – a device with parts that, at best, work at cross purposes.

Furthermore, the Examiner fails totally to explain how one skilled in the art would go from this combination of Halyak and Pardey et al. to Applicants' system for treating people suffering from insomnia when he concludes:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a sleep monitoring system similar to that of Halyak with an insomnia monitor similar to that of Pardey in order to provide a system that separates the levels of sleep of an individual and provides proper treatment to the patient based on their wake/sleep state.

This unsupported conclusory statement does not meet the burden of establishing a *prima facie* case of obviousness. Furthermore, the Examiner has failed to properly apply the obviousness criteria of *KSR International Co. v. Teleflex Inc.*, as detailed below. See Examination Guidelines for Determining Obviousness under 35 U.S.C. 103 in view of the Supreme Court Decision in *KSR International Co. v. Teleflex, Inc.* at page 57529 (attached).

Combining Prior Art Elements According to Known Methods to Yield Predictable Results

Halyak teaches an alarm clock and Pardey et al. teach an insomnia monitor. Pardey et al.'s insomnia monitor would have no known application in Halyak because Halyak's user does not have insomnia – he or she is sleeping and needs to be awakened! There is no known method for combining an insomnia monitor and an alarm clock to yield any predictable

result, let alone Applicants' claimed invention of implementing specific behavioral treatments for insomnia as set forth in the amended claims.

A Simple Substitution of One Known, Equivalent Element for Another to Obtain Predictable Results

Neither reference differs from the claimed system by the mere substitution of some components with other components.

The Use of Known Techniques to Improve Similar Devices in the Same Way

Neither the Halyak device nor the Pardey et al. device is a "base" device upon which the claimed invention is an improvement. Alarm clocks are not improved by combining them with insomnia monitors.

Something "Obviousness to Try" -- Choosing From a Finite Number of Predictable Solutions

Understandably, the Examiner makes no argument that the present invention is "obvious to try." No finite number of predictable solutions is identified.

Known Work in One Field of Endeavor that Prompts Variations of it for Use in Either the Same Field or a Different One Based on Design Incentives or Other Market Forces if the Variations Would Have Been Predictable to One of Ordinary Skill in the Art

None of the cited art comprises a similar or analogous device. Halyak is an alarm clock and Pardey et al. is an insomnia monitor. There were no design incentives or market forces that would prompt the adaptation of either (alone or together) to the implementation of behavioral therapies to treat insomnia in accordance with the present invention.

A Teaching Suggestion or Motivation to Combine Prior Art Teachings (i.e., the "TSM" Test)

There is no teaching, suggestion or motivation to combine an alarm clock as in Halyak with an insomnia monitor as in Pardey et al. and furthermore the combination does not remotely yield the claimed invention.

In re Appln. of Kaplan, Richard
Application No. 10/790,885

This application is considered in good and proper form for allowance, and the Examiner is respectfully requested to reconsider the pending rejections and to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

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Date: September 8, 2008

CH01/ 25212312.10